



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/038,894 03/11/98 STOUGHTON

R 24730-2202

HM22/0130

STEPHANIE L. SEIDMAN
HELLER EHRMAN WHITE & MCAULIFFE
4250 EXECUTIVE SQUARE, 7TH FLOOR
LA JOLLA, CA 92037-9103

EXAMINER

MELLER, M

ART UNIT	PAPER NUMBER
----------	--------------

1651

21

DATE MAILED:

01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/038,894

Applicant(s)

STOUGHTON ET AL.

Examiner

Michael V. Meller

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-24 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 and 32-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

The request filed on 12/19/2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/038,894 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restrictions

Applicant's election with traverse of Group III, claims 19-24 in Paper No. 12 is acknowledged. In paper number 12, applicant did not traverse the restriction requirement. Now, applicant in paper number 20 does traverse the requirement. The traversal is on the ground(s) that applicant can obtain three patents which would prevent the Office from holding obviousness-type double patenting rejections. This is not found persuasive because the methods of Groups II and VI require assaying for cell activation levels which are not required in Group III and further, Groups II and VI require "if elevated", that an activation lowering therapy be used which is not required in Group III. Group VI does not require that such therapy is administered, "prior to commencing further treatment for the disease or condition" whereas Group II does require such a limitation. Group IV is related as an apparatus to the processes and a materially different apparatus can be used such as a dialysis machine.

Art Unit: 1651

Thus, claims 10-18 and 32-38 stand withdrawn from further consideration by the examiner as being drawn to non-elected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is confusing since the phrase, "prior to effecting treatment for the disorder" is not clear. The administration of a protease inhibitor is in itself a treatment to a patient. Thus, the above phrase is confusing.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1651

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al., *The Journal of International Medical Research*, 1991, 19, 348-350 and Okada et al., *The Journal of International Medical Research*, 1991, 19, 234-236.

Both references disclose that islets contain antibodies which cause complement activation associated with insulin dependent diabetes mellitus, and complement activation can be inhibited by administering a protease inhibitor. Okada et al., *The Journal of International Medical Research*, 1991, 19, 348-350, teaches administering nafamostat mesylate (a protease inhibitor) in conjunction with insulin which is a treatment for diabetes.

It would have been obvious to add the inhibitor immediately before administering the insulin since it would have been expected that the same result would have been obtained when adding the inhibitor immediately before or at the same time or immediately thereafter. To add the inhibitor immediately before the insulin would have been a matter of obvious choice depending on individual choice and convenience.

Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yonekura et al., Yanamoto et al., or Murohara et al. (*J. of Pharmacol. And Experimental Therapeutics*, 274 (3): 1246-1253, 1995) in view of Okada et al., *The Journal of*

Art Unit: 1651

International Medical Research, 1991, 19, 348-350 and Okada et al. , *The Journal of International Medical Research*, 1991, 19, 234-236 .

Yonekura et al., Yanamoto et al., or Murohara et al. (*J. of Pharmacol. And Experimental Therapeutics*, 274 (3): 1246-1253, 1995) disclose administering a protease inhibitor when treating disorders. In view of the Okada et al. references, it would have been obvious to add the inhibitor in combination with a treatment for the condition since Okada et al., *The Journal of International Medical Research*, 1991, 19, 348-350 teaches adding insulin in combination with a protease inhibitor.

It would have been obvious to add a protease inhibitor immediately before administering the treatment, since it would have been expected that the same result would have been obtained when adding the inhibitor immediately before or at the same time or immediately thereafter. To add the inhibitor immediately before the treatment would have been a matter of obvious choice depending on individual choice and convenience.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 10:30am-7:00pm.

Art Unit: 1651

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

MVM
January 12, 2001


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1257